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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,433	04/20/2001	Claude Jarkae Jensen	10209.56	1737

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,433

Applicant(s)

JENSEN ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,11,12,22 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,8,11,12,22 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Receipt of Request of Continued Examination, Amendments to Claims, and Applicant's Arguments received January 28, 2004 is acknowledged. Claims **1, 7-8, 11-12, 22, and 27** are pending in this application. Claims 2-6, 9-10, 13-21, 23-26, 28-30 stand cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7-8, 11, and 27 are under 35 U.S.C. 103(a) as being unpatentable over JP2000-095663 to Kondo et al by itself or in view of Elkins (Hawaiian Noni, 1998).

JP teaches a plant extract such as *Morinda citrifolia* for external use. These plant extracts have various properties such as skin whitening abilities, antioxidants effects, and antimicrobial effects, which make them effective for external use. See abstract. The plant extract is utilized in the amount of 0.0005-5% and JP discloses the use of instant *Morinda citrifolia* in the amount of 4.8%. Note Table 2 and page 4 of the translation. The plant extract is extracted from the branch, trunk, bark, bloom, fruit, roots, or other dry matters. The fruit is exemplified. See page 3. The external applications taught are milky lotion, cream, a pack, foundation, lipstick, shampoo, and conditioner and in the form of a

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liquid, salve, gel, etc. See page 2 and examples. Kondo et al teach additives such as lower alcohols, polyhydric alcohols, oily components (paraffin, squalene, cetyl alcohol), antioxidants, surfactants, thickeners, astringents, UV absorbents (octyl methoxycinnamate), vitamins, etc. in the cosmetic compositions. See examples and page 4. Examples teach the instant additives.

*It should be noted that linoleic acid and xeronine are inherent properties of *Morinda citrifolia*.

JP does not specify the part of the fruit utilized, i.e. the fruit seed oil or the fruit juice.

Elkins teaches the usage of noni for over hundreds of years for its therapeutic actions (antimicrobial, antioxidant, and emollient benefits). Elkins teaches that all parts of the noni plant such as the fruit, the seeds, bark, leaves, and flowers are utilized. See page 9-11. One of the most prevalent uses of noni is as a skin healing agent due to the presence of pro-xeronine and the skin's response to it. See page 30.

Although, JP does not specify the part of the *Morinda citrifolia* fruit utilized, it is deemed obvious to one of ordinary skill in the art to utilize any part of the *Morinda citrifolia* extract in the cosmetic composition. One would be motivated to do so since JP teaches any part of the plant may be utilized and it will have the cosmetic benefits of skin whitening abilities, antioxidant effects, and antimicrobial effects. Therefore, one would be motivated to utilize the fruit juice and oil for an additive effect.

Furthermore, one would look to the teachings of the prior art, i.e. Hawaiian Noni and its uses of noni, and note that all the parts of the noni plant provide beneficial

effects to the skin. Therefore, one would be motivated to combine the various plant parts and expect an additive effect on the skin.

In regards to claim 11, one would be motivated to manipulate the concentration of the additive depending on the desired form, i.e. a cream, salve, stick, or ointment, of the cosmetic. This is viewed as a manipulatable parameter known to those skilled in the art.

Claims 11-12 and 22 are under 35 U.S.C. 103(a) as being unpatentable over JP2000-095663 to Kondo et al by itself or in view of Elkins (Hawaiian Noni, 1998) in further view of Lane (5,503,825).

JP teaches a plant extract such as *Morinda citrifolia* for external use. These plant extracts have various properties such as skin whitening abilities, antioxidants effects, and antimicrobial effects, which make them effective for external use. See abstract. The plant extract is utilized in the amount of 0.0005-5% and JP discloses the use of instant *Morinda citrifolia* in the amount of 4.8%. Note Table 2 and page 4 of the translation. The plant extract is extracted from the branch, trunk, bark, bloom, fruit, roots, or other dry matters. See page 3. The external applications taught are milky lotion, cream, a pack, foundation, lipstick, shampoo, and conditioner. See page 2. Kondo et al teach additives such as lower alcohols, polyhydric alcohols, oily components, antioxidants, surfactants, thickeners, astringents, UV absorbents, vitamins, etc. in the cosmetic compositions. See examples and page 4. Examples teach the instant additives.

*It should be noted that linoleic acid and xeronine are inherent properties of *Morinda citrifolia*.

Elkins teaches the usage of noni for over hundreds of years for its therapeutic actions (antimicrobial, antioxidant, and emollient benefits). Elkins teaches that all parts of the noni plant such as the fruit, the seeds, bark, leaves, and flowers are utilized. See page 9-11. One of the most prevalent uses of noni is as a skin healing agent due to the presence of proxeronine and the skin's response to it. See page 30.

JP does not specify the instant additives (ozokerite) or the concentration of the white petrolatum.

Lane teaches a lip balm composition containing aloe and salt. Lane teaches conventional additives and vehicles for the inventive aloe/salt component. These conventional additives are petroleum, silicon oils, paraffin, beeswax, ozokerite, cetyl alcohol, isopropyl myristate, fatty acids, UV absorbers such as salicylic acid derivatives, derivatives of cinnamic acids, and benzophenone derivatives (col. 4, lines 15-62) and the form may be stick, salve, cream, or ointment. Example 2 teaches a lip balm base that contains 44% petrolatums, 0.1% lanolin, 0.5% cetyl alcohol, 1.5% padimate, and 1% isopropyl myristate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Lane and utilize the instant additives and concentrations. One would be motivated to do so since Lane teaches a conventional lip balm base known in the art and utilizes the conventional lip balm base with the inventive aloe/salt component. Therefore, although Kondo et al teach a lipstick composition but do not exemplify a lipstick, one would be motivated to look to the prior art and utilize a conventional lip base with the expectation of similar results.

Claims 1, 7-8, 11, and 27 are under 35 U.S.C. 103(a) as being unpatentable over Tahitian Noni Products (<http://www.noni-now.com>, copyright 1998-2003) by itself or in view of JP2000-095663 to Kondo et al.

Tahitian Noni discloses that noni (*Morinda citrifolia*) products combine the benefits of Tahitian noni juice and Tahitian noni oil that nourishes the skin at the cellular level. The cite states that the noni juice delivers soothing and renewing benefits to the skin and the oil contains linoleic acid and essential fatty acids to nourish the skin and dry spots (Note Tahitian Noni essential oil). The reference teaches an SPF lip balm containing noni oil. Lastly, the reference teaches the combination of the juice and oil in Tahitian Noni Skin Supplement and Body Balance Cream.

The reference does specify percentages in the topical formulation.

JP teaches a plant extract such as *Morinda citrifolia* for external use. These plant extracts have various properties such as skin whitening abilities, antioxidants effects, and antimicrobial effects, which make them effective for external use. See abstract. The plant extract is utilized in the amount of 0.0005-5% and JP discloses the use of instant *Morinda citrifolia* in the amount of 4.8%. Note Table 2 and page 4 of the translation. The plant extract is extracted from the branch, trunk, bark, bloom, fruit, roots, or other dry matters. See page 3. The external applications taught are milky lotion, cream, a pack, foundation, lipstick, shampoo, and conditioner. See page 2.

Although the Noni products fail to disclose the amount of the *Morinda citrifolia* juice and oil, the mere difference in concentration as the sole criteria for patentability for subject matter encompassed by the prior art is not supported in the absence of

unexpected data. See MPEP 2144.05. Furthermore, since the Noni lip balm contains the same critical ingredients for the same functional purpose and absent the applicant's demonstration of the criticality to the concentration of the components, it is deemed that concentration is a manipulatable parameter known to those skilled in the art at the time the invention was made.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teaching of Kondo et al and utilize the instant range of the *Morinda citrifolia*. One would be motivated to do so since Kondo et al teach cosmetics such as a lipstick or face cream containing *Morinda citrifolia*. Further, Kondo teaches the medicinal extract is obtained from any part of the plant. Thus, one would be motivated to utilize the instant range with the expectation of similar results.

Response to Arguments

Applicant argues that the Tahitian Noni Advertisement fails to disclose or suggest any particular components of the suggested lip balm. Applicant argues that the body Balance Cream in the Advertisement does not render the instant invention obvious since the formulation is not for the lips. It is argued that "lips are not really skin" and thus skin products are not suited for the skin.

Applicant's arguments have been fully considered but they are not persuasive. It should be first noted that "lip balm" is a preamble has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble

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for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It should also be noted that although there are differences between the skin and lips, the examiner points out that the lips are classified as skin made of epidermis and the dermis. In determination of non-analogous art, the examiner considers factors such as, the prior art teaches a non-toxic composition for topical application. Additionally, the composition is applied to the epidermis to moisturize it. Thus, it is quite reasonable to assert that the references utilized by the examiner are analogous art. It also should be noted for the record that Tahitian Noni does in fact specifically teach a lip balm. Further, the examiner notes that the website that has been cited by applicant is nonexistent.

Secondly, the examiner points out that the website Advertisement clearly states, "Morinda proprietary formula combines the benefits of the raw Tahitian Noni Juice and Tahitian Noni oil." Therefore, the components of the cosmetic composition such as the lip balm and body balance cream are given. The only deficiency of the prior art is the concentration and absent the criticality of applicant's range, it is deemed an obvious parameter since the prior art composition are utilized for same purpose as applicant: for topical application for moisturizing the skin.

Claims 1, 7-8, 11-12, 22, and 27 are under 35 U.S.C. 103(a) as being unpatentable over Tahitian Noni Products (<http://www.noni-now.com>, copyright 1998-2003) in view of Pelle et al (6,136,301).

Tahitian Noni discloses that noni products combine the benefits of Tahitian noni juice and Tahitian noni oil that nourishes the skin at the cellular level. The cite states that the noni juice delivers soothing and renewing benefits to the skin and the oil contains linoleic acid and essential fatty acids to nourish the skin and dry spots (Note Tahitian Noni essential oil). The reference teaches an SPF lip balm containing noni oil. Lastly, the reference teaches the combination of the juice and oil in Tahitian Noni Skin Supplement and Body Balance Cream.

The reference does specify percentages in the topical formulation.

Pelle et al teach a natural lip product for repairing chapped, cracked lips (col. 1, lines 10-25). Pelle teaches the use of free fatty acids (5-40%) such as oleic and palmitic acid since these are the primary naturally occurring free fatty acids in the stratum corneum (col. 3, lines 40-56). A wax base "known in the art" is formulated from waxes and oils. Waxes such as beeswax, ozokerite or paraffin and plant or animal oils are taught in the amount of 1-20% (col. 4, lines 38-41). Sunscreens such as zinc oxide are taught. See column 5, line 1. Pelle teaches the use of active agents such as anti-irritants in the composition (col. 5, line 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Tahitian Noni Products and Pelle et al. One would be motivated to look at the teachings of Pelle since Pelle et al provide the general guidance in formulating a moisturizing lip product. Pelle teaches using natural oils containing essential fatty acids in the instant amount and Tahitian Noni teaches noni is heals, soothes, and nourishes the skin and the oil contains fatty acids such as oleic

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and palmitic acids. Therefore one would expect similar results since both references teach moisturizing lip formulations with essential fatty acids.

Although the Noni products fail to disclose the amount of the *Morinda citrifolia* juice and oil, the mere difference in concentration as the sole criteria for patentability for subject matter encompassed by the prior art is not supported in the absence of unexpected data. See MPEP 2144.05.

Response to Arguments

Applicant does not address Pelle et al specifically and argues the merits of Tahitian Noni. The arguments pertaining to Tahitian Noni have been addressed above.

Conclusion

All claims remain rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

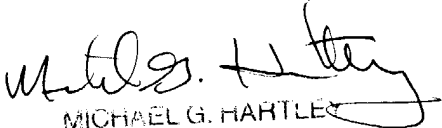
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

April 14, 2004


MICHAEL G. HARTLEY
PRIMARY EXAMINER